

CLAIMS

1. A reagent useful in immunoassays, comprising a direct particulate label co-sensitised with

(i) a specific binding agent having specificity for an analyte or analyte analogue, and

(ii) a non-specific protein which can participate in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte or analyte analogue is accomplished.

*An assay device*

2. ~~A reagent~~ according to claim 1, wherein said first specific binding agent is an antibody raised in a first species and said non-specific protein is an immunoglobulin from another species.

*An assay device*

3. ~~A reagent~~ according to claim 2, wherein said first specific binding agent is a murine antibody.

*An assay device*

4. ~~A reagent~~ according to claim 2, wherein said non-specific protein is a rabbit immunoglobulin.

*An assay device*

5. ~~A reagent~~ according to claim 1, additionally comprising a second population of said direct particulate label sensitised solely with said non-specific protein.

*An assay device*

6. ~~A reagent~~ according to claim 2, comprising coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.

*An assay device*

7. ~~A reagent~~ according to claim 6, additionally comprising same-coloured latex particles of diameter less

than 0.5 micron sensitised solely with rabbit IgG, the ratio of said co-sensitised particles to said second particles being at least 2:1.

5 8. An assay device according to claim 7, wherein said ratio is about 3:1.

10 *Sub 1* 9. An assay device of the type wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result, wherein said labelled reagent is as claimed in claim 1.

15 10. An assay device according to claim 9, wherein said detection zone contains an immobilised specific binding agent which acts as a direct or indirect capture means for said analyte or analyte analogue but which does not bind to said non-specific protein, and said control zone contains a specific binding agent which binds said non-specific protein but does not bind said specific binding agent co-sensitised on said ~~first particle~~ *particulate direct label*.

20 *a* 11. An assay device according to claim 9 *or claim 10* wherein said detection zone contains an immobilised specific binding agent which acts as a direct or indirect capture means for hCG, said control zone contains an immobilised anti-rabbit IgG antibody, and said labelled reagent is coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.

25 *Sub D+1*

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*add C'*